DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA CERTIFIED MAIL

WARNING LETTER

FLA-03-42

August 21, 2003

William S. Hicks, President
HQ, Inc.
208-210 9th Street Drive West
Palmetto, Florida 34221

Dear Mr. Hicks:

During an inspection of your establishment located in Palmetto, Florida on June 9 -10, 2003, Investigator Leo Lagrotte determined that your establishment manufactures electronic, ingestible temperature sensors. This product is used by health practitioners and researchers to monitor core body temperatures in patients exceeding six (6) hours and is a device, as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(h)].

The investigator documented significant violations from the Quality System (QS) Regulations, Title 21, Code of Federal Regulations (CFR), Part 820, and the Medical Device Reporting regulations, Title 21, CFR, Part 803. These violations cause the devices you manufacture to be adulterated within the meaning of Section 501(h) [21 U.S.C. § 351(h)] and misbranded within the meaning of Section 502(t)(2) of the Act [21 U.S.C. § 352(t)(2)].

Specifically, the investigator noted the following violations:

1. Your firm failed to conduct quality audits in accordance with your own procedures to assure your quality system is in compliance with established requirements and to determine the effectiveness of your quality system as required by 21 CFR 820. 22. The investigator determined that your quality manual requires audits to be performed on an annual basis; however, none have been performed and/or documented (FDA 483, Item #6).

2. Your firm failed to establish and maintain procedures for implementing corrective and preventive actions (CAPA) and to document all activities as required by 21 CFR 820.100(a). The investigator determined that you have not established written CAPA procedures (FDA 483, Item #1).

3. Your firm failed to establish and maintain procedures that ensure that all incoming components conform to specified requirements as required by 21 CFR 820.50. The investigator determined that inspection and verification of a component's fitness was being determined by the contract manufacturer contrary to established procedures (FDA 483, Item #2).

4. Your firm failed to establish and maintain complete requirements for the acceptance and rejection of incoming product as required by 21 CFR 820.80(b). The investigator determined that incoming inspection procedures require 100% inspection or statistical-based sampling technique(s) to ensure conformance to specified requirements; however, these procedures were not established and maintained (FDA 483, Item #3).

5. Your firm failed to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit as required by 21 CFR 820.198. The investigator determined that service requests were not included, evaluated and documented as complaints and, therefore, were not evaluated to determine whether they contained reports of an adverse event or malfunction that was required to be reported to FDA as a medical device report (MDR) (FDA 483, Item #4).

6. Your firm failed to establish and maintain written MDR procedures as required by 21 CFR 803.17.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts..

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the steps you have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any

underlying systems problems necessary to assure that similar violations will not recur. Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Emma Singleton
Director, Florida District